

**UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION**

UNIMED PHARMACEUTICALS, INC.,
a Delaware Corporation, and
LABORATORIES BESINS
ISCOVESCO, a Delaware Corporation,

Plaintiffs,

v.

PADDOCK LABORATORIES, INC.,
a Minnesota Corporation,

Defendant.

**Civil Action No.
File No. 1:03-CV-2503-TWT**

**MEMORANDUM IN SUPPORT OF PADDOCK'S MOTION FOR
PARTIAL SUMMARY JUDGMENT OF INVALIDITY OF CLAIMS
1-30 OF THE '894 PATENT AS LACKING A WRITTEN
DESCRIPTION AS REQUIRED BY 35 U.S.C. § 112, FIRST
PARAGRAPH WITH RESPECT TO THE CLAIMED RANGES OF
SODIUM HYDROXIDE**

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October 18, 2005

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I. Introduction

The present action was brought by Unimed under U.S. Patent No. 6,503,894 (the “‘894 patent”) alleging that Paddock Laboratories, Inc. (“Paddock”) infringed the claims of the ‘894 patent by the filing of its ANDA which sought approval from the FDA for the manufacture and sale of a generic version of Unimed’s product Androgel. The Androgel formulation is described in Table 5 of the ‘894 patent. However, due to a series of colossal blunders during both the preparation and the prosecution of the patent application which became the ‘894 patent, a number of which are described in Paddock’s claim construction briefs and in Paddock’s motion for partial summary judgment of invalidity of the Certificate of Correction to the ‘894 patent, there is no claim in the entire ‘894 patent whether as issued or as the claims were attempted to be corrected by the Certificate of Correction, which covers either Androgel or Paddock’s proposed generic equivalent.

The present motion is directed to the invalidity of claims 1-30 of the ‘894 patent because the claims do not have a written description which supports the ranges recited in those claims of sodium hydroxide, which is an ingredient in the claimed compositions. The written description requirement of 35 U.S.C. § 112, first paragraph, and its corollary, 35 U.S.C. § 132’s prohibition on the introduction of new matter, prevent applicants from obtaining valid claims to subject matter that

is not supported by their patent application as originally filed, such as where, as here, an applicant later seeks to claim a range or ranges for a particular ingredient even though there is no support in the patent application as originally filed for such a range or ranges.

Here, the only reference to sodium hydroxide in the application as filed was to a particular amount of that ingredient which, as related by Table 5 of the patent, is the amount in Androgel. Therefore, as filed, there was no range of sodium hydroxide referenced anywhere in the specification or in the original proposed claims of the patent application. Later, during patent prosecution, claims were added that recited ranges for the proportional amount of sodium hydroxide in the claimed compositions. In addition to finding no support in the original disclosure, these ranges were constructed around an erroneous calculation presented by Unimed to the Patent Office in support of those ranges which was off by a factor of 100.

As a matter of law, these sodium ranges (whether as issued or as purportedly corrected by the Certificate of Correction) clearly are not supported by the written description of the original disclosure and constitute new matter, hence invalidating those claims.

II. Relationship of This Motion To Paddock's Motion For Summary Judgment Declaring The Certificate of Correction Invalid And To Issues Of Claim Construction

There are a number of issues, relating to claim construction, invalidity of the Certificate of Correction and invalidity of claims 1-30 of the patent, that all revolve around the reference to sodium hydroxide in those claims and to the recited ranges for that ingredient in the claimed composition. In addition, the essential intrinsic record evidence relating to these issues, as found in the claims, specification and prosecution history is the same or substantially the same. Accordingly, while there are different legal issues raised in relation to the sodium hydroxide element of the claims, each of these issues is closely related and rest to a large extent on the same aspects of the intrinsic record.¹ Accordingly, Paddock proposes that the present motion be argued, together with claim construction and the invalidity as a matter of law of the Certificate of Correction at the *Markman* proceedings to be scheduled in this matter.

III. Statement Of Material Facts As To Which There Is No Genuine Issue

The '894 patent, the Certificate of Correction and the prosecution history are annexed as Exhibits A, B and C, respectively, to the Appendix which accompanied

¹ For this reason, the Statement Of Material Facts Not In Genuine Issue in this memorandum is in part the same as that section of Paddock's brief in support of its motion directed to the invalidity of the certificate of correction.

Paddock's Opening Brief on Claim Construction. An index to the prosecution history is found at App. C, FW002-003.²

A. The Ranges Of Sodium Hydroxide Recited In The Claims Of The '894 Patent Do Not Appear In The Specification Of The Patent

There are five independent claims in the '894 patent. The claims are found at columns 49-52 of the patent. App. A. Four of these, claims 1, 9, 10 and 18, recite sodium hydroxide as an ingredient in the claimed composition and provide a range for the proportional amount of that ingredient. Accordingly, all of the dependent claims that depend from one of those claims also recite a range for that ingredient.

Specifically, claims 1, 10 and 18(a) all recite a range of "about 1% to about 5%" sodium hydroxide. Claim 9 recites a range of "about 1% to about 3%" sodium hydroxide. Claims 2-7 depend from, and therefore incorporate the requirements of, claim 1. Claims 11-17 depend from, and therefore incorporate the requirements of, claim 10.

² Exhibits referenced in this motion are annexed to the Appendix which accompanied Paddock's August 12, 2005 Opening Claim Construction Brief and its Reply Claim Construction Brief (certain components of which were filed under seal).

The other independent claim, claim 31, does not recite sodium hydroxide as an ingredient of which the composition of claim 31 is stated to “consist essentially of”.

There is no reference to these ranges or to any other range of sodium hydroxide in the specification of the ‘894 patent.

B. Not Only Was There Was No Reference In The Specification To Ranges Of Sodium Hydroxide In The Patent As Originally Filed, But None Of The Claims As Originally Filed Recited Sodium Hydroxide At All

The original patent application that resulted in the ‘894 patent was filed on August 30, 2000. App. C, Tabs 3-7. None of the original claims recited sodium hydroxide as an ingredient in the claimed composition. *See* App. C, Tab 3.

Nowhere in the specification (App. C, Tab 4) (whether as originally filed or as in the issued patent) was there a range provided for the amount sodium hydroxide. The only reference to sodium hydroxide in the specification is in Table 5 (App. A, col. 13, App. C, Tab 4, FW126) which is the formula for the only specific composition described in the specification, namely, Androgel®. It reads:

TABLE 5

<u>Composition of AndroGel®</u>	
SUBSTANCE	AMOUNT (w/w) PER 100g Of GEL
Testosterone	1.0g
Carbopol 980	0.90g
Isopropyl myristate	0.50g
0.1 N NaOH	4.72g
Ethanol (95% w/w)	72.5g*
Purified water (qsf)	100g

*corresponding to 67 g of ethanol.

“NaOH” is the chemical name for pure sodium hydroxide, which exists in solid form. App. L ¶ 45 (Allen 4/22/05 Expert Report). In the expression “0.1 N”, N is an abbreviation for the term normal which in this context refers to a solution having a concentration of one gram equivalent of solute per liter. *Id.*; *see also*, the relevant definition of normal at Merriam-Webster Online. Therefore, in this context, the term “0.1 N NaOH” refers to a particular normality or concentration of sodium hydroxide in solution.

Immediately after Table 5 in the patent is the following paragraph:

One skilled in the art will appreciate that the constituents of this formulation may be varied in amounts yet continue to be within the spirit and scope of the present invention. For example, the composition may contain about 0.1 to about 10.0 g of testosterone, about 0.1 to about 5.0 g Carbopol, about 0.1 to

about 5.0 g isopropyl myristate, and about 30.0 to about 98.0 g ethanol. [App. A, col. 13, lines 36-43]

There is no mention in this passage, or anywhere else in the specification as filed of any range of amounts of sodium hydroxide. Again, the only reference to sodium hydroxide in the entire patent application as originally filed, including the original proposed claims, is the reference in Table 5 to the amount in Androgel, i.e., 4.72 g of 0.1 N NaOH.

C. Sodium Hydroxide Ranges Were First Introduced In The Claims By A February 2002 Amendment

Since neither the specification nor the original claims contained a reference to sodium hydroxide, all later claims which set forth such a reference, including those which were later added claiming a range of sodium hydroxide, were added by amendment.

On October 19, 2001, applicants filed an Amendment and Response to June 19, 2001 Office Action that, among other things, added two new dependent claims, 45 and 63, that mark the first appearance of a reference to sodium hydroxide in any of the proposed claims. Applicants did not comment on these claims in the Remarks section of its submission. App. C, Tab 14 (new claims 45 and 64 at FW318 and FW320). In each of these new claims, the term sodium hydroxide appears by itself without any indication of a range; e.g, proposed claim 45 reads:

“The composition as recited in Claim 1 further consisting essentially of sodium hydroxide.”

In a Supplemental Amendment, dated December 21, 2001, various claims were added and others cancelled. Among those cancelled without comment were proposed claims 45 and 64 which had first introduced a reference to sodium hydroxide in the proposed claims. App. C, Tab 19, FW374-390. Upon the cancellation of those claims by this amendment, none of the proposed claims contained a reference to sodium hydroxide until the February 2002 amendment discussed below.

Claims referring to a range of sodium hydroxide were first introduced through an amendment in February 2002, titled Supplemental Amendment II (February 8, 2002). App. C, Tab 21 at FW 394-439. See e.g. proposed claims 47, 61, 78, and 97 at App. C., Tab 21 at FW408-12. (These proposed claims later became claims 1, 9, 10 and 18 of the issued patent.) These proposed claims set forth one of two ranges for a proportionate amount of sodium hydroxide in the claimed composition: either about 1% to 5% (e.g. proposed claims 47, 78 and 97) or about 1% to 3% (e.g. proposed claim 61). *Id.*³

³ None of these proposed claims referencing sodium hydroxide contain the modifier 0.1 N. *Id.* In fact, at no point during the prosecution of the application did any claim reciting sodium hydroxide contain the modifier 0.1 N or any other

D. The February 2002 Amendment That Added Claims Reciting A Range Of Sodium Hydroxide Included A Calculation Offered To Support The New Claims That Purported To Convert 4.72 Grams Of 0.1 N Sodium Hydroxide In Solution To 1.8% Pure Sodium Hydroxide

To support these new claims reciting not only sodium hydroxide but also these ranges of amounts of sodium hydroxide, the applicants presented, in the same Supplemental Amendment II, a calculation purporting to convert the amount of sodium hydroxide in Androgel, when expressed in terms of 0.1 N, into the equivalent amount of pure sodium hydroxide, as shown in the following excerpt from the pertinent table in that submission:

Claim	Support in Specification
47-48, 51-52, 54-57	pp. 23-27; Table 5, p. 26. Note that 4.72g of 0.1N NaOH=about 1.8g NaOH in 100g of gel, or about 1.8%

App. C, Tab 21 at FW419 (emphasis added). Other portions of this table also point to Table 5, p. 26 (i.e., of the original specification) as supporting the other proposed claims (61, 78 and 97) to which a reference to certain ranges of sodium hydroxide was added by this amendment. *Id.*

The highlighted portion clearly purports to show the conversion of the amount of sodium hydroxide in Androgel® (as shown in Table 5 of the

modifier or indication that the recited amount of sodium hydroxide was in solution or that it was anything but the pure, solid chemical compound NaOH.

specification as originally filed and as issued), i.e., 4.72 grams of 0.1 N NaOH (in solution), to an amount of pure (solid) NaOH: a value which is given as 1.8%. This 1.8% NaOH value is roughly in the middle of the ranges (1%-5% and 1%-3%) given for sodium hydroxide in the proposed claims added by this amendment and is particularly close to the midpoint of the about 1% to 3% range of proposed claim 61. Proposed claim 61 (later issued as claim 9) also contains the narrowest ranges of the other ingredients in the claimed composition as compared to the other independent claims and is drawn more closely than any of the other claims around the proportional ingredient amounts given for Androgel® in Table 5 of the specification.⁴

In view of this prosecution history, including the conversion calculation proffered in support of the newly added claims reciting a range of sodium hydroxide, there can be no dispute that these proposed claims were intended to, and did, recite amounts of pure (solid) sodium hydroxide and not, therefore, in solution or in any concentration or normality. Plaintiffs agree that these claims, as

⁴ Thus, while not a fact necessary to grant this motion, it is evident applicants constructed the two claimed ranges of sodium hydroxide (1-3% and 1-5%) around what they (erroneously) thought was the amount of pure sodium hydroxide in AndroGel® (1.8%), which is squarely in the middle of the narrower range.

issued, recite pure sodium hydroxide. See Pl. 7/25/05 Memorandum on Claim Construction at 19.

E. The Sodium Hydroxide Conversion Calculation Offered In Support Of The Proposed Claims Reciting Ranges Of Sodium Hydroxide Was Wrong By Two Decimal Places (A 100-Fold Error), An Error Which Is Not Cured By Applying 0.1 N To The Incorrect Result As The Certificate Of Correction Does

As plaintiffs agree, the conversion calculation shown above is in fact mathematically incorrect; it is off by two decimal places, a factor of 100. It should have said 0.018 g NaOH is equivalent to 4.72 g of NaOH, instead of 1.8 g. See Pl. 7/25/05 Memorandum on Claim Construction at 29. As noted above, normality refers to a solution having a concentration of one gram equivalent of solute per liter.⁵ Mathematically, applying the term 0.1 N to the incorrect result of the conversion calculation does not correct it; the only way to correct it is by moving the decimal point on the incorrect result of 1.8 g NaOH two places to the left so as to give the correct conversion of 0.018 g NaOH. Put differently, a calculation meant to convert a certain amount of 0.1 N sodium hydroxide (which by definition

⁵ In Table 5, the sodium hydroxide content in Androgel[®] is expressed as 4.72 g 0.1 N NaOH per 100 g of gel. 0.1 N sodium hydroxide means an aqueous solution containing 0.1 equivalent weight of NaOH per liter of solution. The equivalent weight of NaOH is 40 g. A 0.1 N NaOH solution has 0.1 equivalent weight of NaOH per liter of solution, or 4 g of NaOH (0.1 x 40) per liter. Assuming a density of water of 1 g/ml, a liter of the solution weighs approximately 1000 g. Thus, 1 g of 0.1 N NaOH solution contains 0.004 g NaOH (4/1000). App. L ¶ 46 (4/22/05 Allen Expert Report).

is in solution) to pure sodium hydroxide and which is off by a factor of 100 cannot be corrected by simply adding the 0.1 N term to the result of the incorrect conversion calculation. For example, 1.8 g of 0.1 N NaOH (in solution) (the incorrect conversion result with 0.1 N applied to it as Plaintiffs have sought to correct the claims) does not equal to 0.018 g NaOH (solid/pure) (which would have been the correct result of converting 4.72 g 0.1 N NaOH to pure NaOH). Instead, 1.8 g of 0.1 N NaOH (solution) is equal to 0.0072 g NaOH (pure/solid).⁶

Examining claim 9 as corrected further demonstrates that adding 0.1 N to claims cannot cure the error in the conversion calculation. Plaintiffs contend that this error “could be corrected” by inserting the term 0.1 N before sodium hydroxide in the claims so that the claims will cover Androgel®⁷. But, even with this change claim 9 still, as plaintiffs admit, fails to cover Androgel®. As set forth in Table 5 of the specification, Androgel® contains 4.72 g of 0.1 NaOH. However, it is Plaintiffs’ position that the about 1% to 3% range of claim 9 means concentrations “up to 3.99%” and Plaintiffs admit that claim 9 does not literally cover the sodium hydroxide concentration in Androgel®. Plaintiffs’ 7/25/05 Memorandum on Claim Construction at 22 and 16.

⁶ Using the information in footnote 5 above, 1.8 grams of 0.1 N NaOH (solution) = $1.8 \text{ g} \times (0.1 \text{ equivalent weight}/1000 \text{ ml water} \times 40 \text{ grams NaOH/equivalent weight}) = 0.0072 \text{ g NaOH (solid)}$.

⁷ See Plaintiffs’ 7/25/05 Memorandum on Claim Construction at 29.

There is nothing in the prosecution history to suggest that the applicants intended all of the claims of the patent to cover Androgel®, except claim 9 which, to the contrary, has the narrowest ranges of relative proportions of ingredients of all the claims and is drawn more closely to ingredient proportions of Androgel® than any of the other claims.

In requesting a Certificate of Correction (five months after the patent issued), applicants and their patent counsel represented that:

the mistakes were made in good faith and that the proper language is contained throughout the specification, see, for example, column 13, Table 5 (“0.1 N NaOH”) (sodium hydroxide)). As such, the correction does not involve such changes in the patent that would constitute new matter or would require reexamination. [App. C, Tab 40 at FW596]

Applicants did not present the Patent Office with any facts or arguments to support their assertion that the “mistake” with respect to sodium hydroxide was made in good faith. App. C., Tab 40.

The Certificate of Correction was issued on December 16, 2003. App. B.

F. It Is Undisputed That The Amount Of Sodium Hydroxide In Androgel Could Be Expressed By A Broad Range Of Normalities Other Than 0.1 N

Table 5 (at col. 13) of the patent expresses the amount of sodium hydroxide used in formulation Androgel® in terms of 0.1 N NaOH. There is however, no scientific reason why that concentration, specifically, why that “normality”, must

be used in formulating the composition broadly recited in the claims – even Plaintiffs’ experts agree that one could use many various normalities of solution of sodium hydroxide to produce the desired result, e.g., 0.2 N, 0.3 N or 0.4 N among many. Plaintiffs’ expert Dr. Weiner explained that “setting forth the amount of sodium hydroxide used in the claimed formulation as a 0.1 N solution is just one of an infinite number of ways that the amount of sodium hydroxide claimed in the ‘894 Patent could be expressed.” Weiner Expert Report, App. X, ¶ 45. *See* Barr Dep. Tr., App. DD at 66; Bowman Dep. Tr., App. EE at 150-51, 155, 169-70. *See also* Allen Rebuttal Report, App. M, ¶ 9; Allen Reply Report, App. N, ¶ 9.

IV. Argument

A. The Legal Standard For Summary Judgment

Summary judgment is appropriate where there is no genuine issue of material fact and the movant is entitled to judgment as a matter of law. *See* Fed. R. Civ. P. 56(c); *see Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). Summary judgment should be granted when no reasonable fact finder could return a verdict for the nonmovant. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248-49 (1986).

B. The Written Description Requirement Of 35 U.S.C. § 112 And The New Matter Prohibition Of 35 U.S.C. § 132

The written description requirement of 35 U.S.C. § 112 has two (2) fundamental purposes: (i) to show that the inventor is in possession of the

invention, and (ii) to show that the original application provides “adequate support” for the claims at issue or the material added during the course of prosecution does not violate the “new matter” prohibition of 35 U.S.C. § 112. *See Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 969-70 (Fed. Cir. 2002).

The prohibition against the introduction of new matter in a patent application under 35 U.S.C. § 132 and 251 prevents an applicant from adding information that goes beyond the subject matter originally filed. *See In re Rasmussen*, 650 F.2d 1212, 1214 (CCPA 1981). Thus, the written description requirement prevents an applicant from claiming subject matter that was not adequately described in the specification as filed. New or amended claims which introduce elements or limitations which are not supported by the disclosure (specification) as originally filed violate the written description requirement. Thus, the Federal Circuit has explained that:

The written description requirement and its corollary, the new matter prohibition of 35 U.S.C. § 132, both serve to ensure that the patent applicant was in full possession of the claimed subject matter on the application filing date. When the applicant adds a claim or otherwise amends his specification after the original filing date [as applicants did in this case,] the new claims or other added material must find support in the original specification.

TurboCare Div. of Demag Delaval Turbomachinery Corp. v. General Electric, 264 F.3d 1111, 1118 (Fed. Cir. 2001). In the absence of express or clear implicit support in the original filing: “The fundamental inquiry is whether the material

added by amendment was inherently contained in the original application.”
Schering Corp. v. Amgen Inc., 222 F.3d 1347, 1352 (Fed.Cir.2000).

In order for a disclosure to be inherent, “the missing descriptive matter must necessarily be present in the [original] application's specification such that one skilled in the art would recognize such a disclosure.” *Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 1159 (Fed.Cir.1998). Whether one skilled in the art could arrive at the claimed range, such as through experimentation or because it may be viewed as an obvious variant, is not the proper avenue of inquiry. As the Federal Circuit held in *Lockwood v. American Airlns., Inc.*, 107 F.3d 1565 (Fed.Cir.1997), that is not enough to satisfy the written description requirement:

While the meaning of terms, phrases, or diagrams in a disclosure is to be explained or interpreted from the vantage point of one skilled in the art, all the limitations must appear in the specification. **The question is not whether a claimed invention is an obvious variant of that which is disclosed in the specification.** Rather, a prior application itself must describe an invention, and do so in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention as of the filing date sought.

Id. at 1572(emphasis added); *see also Martin v. Mayer*, 823 F.2d 500, 505 (Fed. Cir. 1987) (“It is not a question of whether one skilled in the art might be able to construct the patentee’s device from the teachings of the disclosure Rather it is a question of whether the application necessarily discloses that particular device”); *In re Certain Doxorubicin and Preparations Containing Same*, 20

U.S.P.Q.2d 1602, 1607 (U.S. Intern. Trade Com'n 1991) (that "a person of ordinary skill in the art might conduct experiments and determine the operative (or optimal) range does not . . . establish that the upper [claimed] limit of 1:4.5 is sufficiently described to indicate it as a parameter of the claimed process", because such an argument confuses the written description requirement with the enablement requirement of 35 U.S.C. § 112).

Thus, the question is not, as Unimed would have it, whether the ranges of sodium hydroxide as recited in the claims (as issued and as corrected) are obvious variants of the amount in Androgel as shown by Table 5 or could be arrived at through experimentation with varying proportions of the ingredients in the claimed composition. Rather, the question is whether there is sufficient support in the specification as originally filed for the later claimed ranges. For the reasons set forth below, the answer to that question is clearly, no.

C. Claims 1-29 Of The Patent Are Invalid As Lacking A Written Description Under 35 U.S.C. § 112 Insofar As They Recite Ranges Of Sodium Hydroxide Which Were Not Referenced In The Specification Or Claims As Filed And Which Are Based On An Incorrect Conversion Calculation

1. Later Added Claims Which Recite A Range Or Ranges For An Ingredient Where Such Ranges Are Not Supported By The Original Disclosure Are Invalid

Applying the analytical framework described above for determining compliance with the written description requirement of § 112 (as opposed to

determining whether obvious variants to exemplified subject matter may be enabled), the Federal Circuit and district courts have found invalid amended claims which recite a range of amounts for a particular ingredient which have no support in the specification as originally filed, such as where, as is the case here, a single example provides a single data point or amount for an ingredient but the applicants later seek to claim a range of amounts for that ingredient. *See In re Lukach*, 442 F.2d 967 (CCPA 1971) (holding that a single example disclosing a copolymer having a Mw/Mn ratio of 2.6 does not alone support a claim range from 2.0 to 3.0 Mw/Mn ratio); *see also Tronzo v. Biomet*, 156 F.3d 1154 (Fed Cir. 1998) (“certainly the single exemplary disclosure of using 93% by weight...provides no support for the recited range...”); *Mobil Oil Corporation v. Amoco Chemicals Corporation*, 779 F.Supp. 1429 (D.Del. 1991) (holding that the disclosure of one example may not support a claim to a specific range).

2. The Original Disclosure Of The ‘894 Patent Provides No Support For Ranges Of Sodium Hydroxide In The Claimed Composition

As described in the Statement of Material Facts section above, the only reference in the specification (both as filed and in the issued patent) to sodium hydroxide is its appearance in the list of ingredients for Androgel® in Table 5 in a specific amount (4.72g). There was no reference to sodium hydroxide in the claims filed with the original application. The references to sodium hydroxide in

the claims (and of course to ranges of the amount of it) came in only later by amendment. See App. C at FW 394-439. So as originally filed there was no disclosure of any ranges for sodium hydroxide in the application.

“The fundamental inquiry is whether the material added by amendment was inherently contained in the original application.” *Schering Corp.*, 222 F.3d at 1352. Clearly there is no express support in the disclosure as originally filed for any range of sodium hydroxide in the claimed composition. Nor is there any implicit support. Again, the sole reference in the entire specification to sodium hydroxide is in the sole example of a specific composition described in the specification, which is to the precise amount of sodium hydroxide in Androgel, i.e., 4.72 g of 0.1 N NaOH. There are no other examples in the specification of other combinations of ingredients that would provide support for some other amount of sodium hydroxide, much less for the later claimed ranges of that ingredient.

Finally, there is no inherent description of such a range since in order to be inherent the range, i.e., the missing descriptive matter, must necessarily be present. “Inherency may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a certain set of circumstances is not sufficient.” *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999) (citations omitted).

Plaintiffs’ experts have concluded that the application as filed supports the claimed range added by amendment. Weiner Rebuttal Report, App. CC, ¶¶ 72-74;

Bowman Report, App. Y, ¶¶ 37-39. However, this conclusion is based on a determination that the missing description would have been obvious to a person of ordinary skill in the art, which, as set forth above, is not a permissible avenue of analysis for this issue, as it is tantamount to attempting to establish inherency by mere possibilities or probabilities.

3. There Is Also No Support In The Original Disclosure Of The '894 Patent For The Specific Ranges Of Sodium Hydroxide Recited In The Claims As Issued, Because Those Ranges Are Based On An Incorrect Calculation In The Prosecution History Purporting To Convert The NaOH In Solution In Androgel To Pure (Solid) NaOH

For the reasons set forth above, as a matter of law, the disclosure of the '894 patent does not contain information to support a claim to a range or ranges of the amount of sodium hydroxide in different permutations of the claimed composition. For additional reasons, it is also the case, as a matter of law, that the specific ranges of sodium hydroxide recited in the claims, as issued and as corrected, are not supported because those ranges are based the erroneous conversion calculation submitted with the February 8, 2002 Amendment.

As set forth above, that Amendment included the addition for the first time of claims reciting ranges of sodium hydroxide. Those proposed claims became issued claims 1, 9, 10 and 18. In support of those claims, Unimed submitted the erroneous calculation that purported to convert the specific amount of sodium

hydroxide in Androgel (4.72 g of 0.1 NaOH, in solution) to the equivalent amount of pure (solid) sodium hydroxide. However, that calculation was wrong by two decimal places because it stated that the equivalent amount of pure NaOH is 1.8% rather than 0.018%. The proposed claims (reciting about 1%-3% and about 1%-5% NaOH) that accompanied this calculation were evidently structured around this erroneous conversion value.⁸

Thus, the original disclosure cannot possibly support the sodium hydroxide ranges in the claims as issued for the additional reason that they were constructed around the erroneous result of the conversion calculation.

* * *

Accordingly, then, for all of the foregoing reasons, the claims as issued which reference ranges of sodium hydroxide, either as independent claims or dependent claims, are invalid under 35 U.S.C. § 112, first paragraph, because, as a

⁸ As will be emphasized in a separate motion *in limine* Paddock intends to file, Unimed should be precluded from arguing about or offering any testimony whatsoever to the contrary as to the sodium hydroxide range and its origin. This is so because during the deposition of Mr. Mahoney, the attorney responsible for prosecuting the patent application, and also during the deposition of Dr. Dudley, one of the inventors of the '894 patent and the one who supervised its prosecution, Unimed asserted attorney-client privilege and directed both witnesses not to answer any questions relating to the basis for the claimed sodium hydroxide range. Mr. Mahoney did admit in his deposition that the express range recited in the claims for sodium hydroxide was not present in the specification, but beyond that was instructed not to answer on the grounds of attorney-client privilege.

matter of law, those ranges find no support in the disclosure as originally filed and therefore lack a written description in the manner required by § 112.

4. There Is Also No Support In The Original Disclosure Of The '894 Patent For The Specific Ranges Of Sodium Hydroxide Recited In The Claims As Corrected

Furthermore, as also discussed in Paddock's motion for summary judgment of invalidity of the Certificate of Correction, it is clear that the insertion of 0.1 N before sodium hydroxide in claims 1, 9, 10 and 18 (as the certificate of correction does) cannot fix those claims (and is not a clearly evident "correction") because applying 0.1 N to the erroneous result of the conversion calculation cannot, mathematically, cure the original error, which is that result of the conversion calculation was erroneously given as 100 times greater than it the correct value. This, of course, is in addition to the fact that Unimed's presentation of the conversion calculation in support of its proposed claims reciting ranges of sodium hydroxide shows that it intended to claim ranges of pure (solid) NaOH (and not ranges expressed in terms of any normality or concentration of solution).

Moreover, because the normality or concentration of sodium hydroxide in the claims could have been expressed in numerous normalities other than 0.1 N, and thus 0.1 N is not inherently required by the disclosure as the only manner in which to express normality even the applicants had intended to express the claimed amounts of sodium hydroxide in solution (which they clearly did not). Therefore,

for this additional reason as well, there is no written descriptive support in the original disclosure in the manner required by 35 U.S.C. § 112 for the claims as purportedly corrected by the Certificate of Correction.

Therefore, insofar as the Certificate of Correction seeks to add 0.1 N to claims 1, 9, 10 and 18 it is invalid as lacking a written description as required by § 112 both because:

(i) the certificate is invalid insofar as it attempts to correct claims having ranges for sodium hydroxide which (whether as originally issued or as corrected) are invalid under § 112 because there is no support in the original disclosure for any ranges of sodium hydroxide; and

(ii) there is no support in the original disclosure for the specific ranges of sodium hydroxide (whether as originally issued or as purportedly corrected) for the additional reason that those ranges (a) were constructed around the erroneous result of the conversion calculation and (b) cannot be corrected mathematically in any event by the insertion of 0.1 N before sodium hydroxide.

Accordingly, for all of these reasons, insofar as the Certificate of Correction seeks to add 0.1 N to claims 1, 9, 10 and 18, the certificate is invalid under § 112.

V. Conclusion

For all of the foregoing reasons, Paddock respectfully requests that the Court grant summary judgment in Paddock's favor holding claims 1-30 of the '894 invalid (both as issued and as purportedly corrected by the Certificate of Correction) because their reference to a range for sodium hydroxide constitutes new matter under 35 U.S.C. § 132 and thus lacks a written description as required by 35 U.S.C. § 112.

Dated: October 18, 2005

Respectfully submitted,

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**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION**

UNIMED PHARMACEUTICALS,
INC., a Delaware Corporation, and
LABORATORIES BESINS
ISCOVESCO, a Delaware
Corporation,

Plaintiffs,

v.

PADDOCK LABORATORIES, INC.,
a Minnesota Corporation,

Defendant.

Civil Action No.

File No. 1:03-CV-2503-TWT

CERTIFICATE OF SERVICE

I hereby certify that on October 18, 2005, a true and correct copy of the foregoing document was filed electronically via CM/ECF in the United States District Court for the Northern District of Georgia, with notice of same being electronically served by the Court, addressed to:

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This 18th day of October, 2005.

_____/s/_____

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